

form of the product has been substituted for the stable, and just as clearly the labels falsely represent the true nature of the wafers involved.

"8. The defendant, Henry J. Johnson, is President and General Manager of the defendant corporation. According to inspectors of the Food and Drug Administration (visiting the defendants' plant) Mr. Johnson is the person responsible for the operation of the plant. He had to be seen before any decision could be made affecting any of the plant's operations.

"9. On the basis of the foregoing facts the defendants and each of them, are guilty on each count of violating the Federal Food, Drug, and Cosmetic Act, as charged.

CONCLUSIONS OF LAW

"1. This Court has jurisdiction of the cause and the parties, pursuant to 21 U.S.C. §§ 331 and 333.

"2. The Vitamin D enrichment wafer involved here is a food. 21 U.S.C. § 321(f).

"3. Under the Federal Food, Drug and Cosmetic Act, a food is adulterated if another product has been substituted in whole or in part therefor. 21 U.S.C. § 342(b)(2).

"4. Under the Federal Food, Drug and Cosmetic Act, a food is misbranded if the labels or labeling for that food are false or misleading in any particular. 21 U.S.C. § 343(a).

"5. The food here was adulterated within the meaning of 21 U.S.C. § 342(b)(2).

"6. The food here was misbranded within the meaning of 21 U.S.C. 343(a).

"7. The food here was adulterated and misbranded when introduced into and while in interstate commerce.

"8. The defendants are responsible for the introduction into interstate commerce of an adulterated and misbranded food.

"9. Intent is not an element of a criminal offense under the Federal Food, Drug and Cosmetic Act.

"10. The defendants and each of them are guilty in each count of violating the Federal Food, Drug and Cosmetic Act as charged.

ORDER FOR FURTHER PROCEEDINGS

"1. Rule 43 of the Rules of Criminal Procedure provides that a defendant corporation may appear by counsel for all purposes and that in prosecutions for offenses punishable by fine, the Court may, with the written consent of the defendant, impose sentence in the defendant's absence. Counsel for the defendant will advise the Court within five (5) days in regard to the defendant's wishes in this connection.

"2. The provisions of Rule 32(c) of the Rules of Criminal Procedure are hereby invoked and the Probation Service of this Court is ordered to make a presentence investigation and report that shall include any prior criminal record of the defendant, if any, and shall also include a report of any civil proceeding that may have been instituted against the defendant in connection with the enforcement of any state or federal statutes, if any.

"3. Counsel will be advised of the date on which sentence will be imposed and defendant will then be afforded an opportunity to make a statement on its own behalf and to present any information in mitigation of punishment. If defendant cares to submit a written statement in that regard before sentence is imposed, it may do so within fifteen (15) days.

"IT IS SO ORDERED."

On 2-14-64, each of the defendants were fined \$150.

29393. Cod liver oil. (F.D.C. No. 48383. S. Nos. 39-908/10 V.)

QUANTITY: 2 bulk drums, 25 cases, 6 doz. 1-oz. btls. each; 29 cases, 3 doz. 2-oz. btls. each; 51 cases, 3 doz. btls. each; and 29 cases, 2 doz. 8-oz. btls. each; at Hato Rey, P.R., in possession of Mendez Laboratories of America, Inc.

SHIPPED: 6-13-62, from Bergen, Norway.

LABEL IN PART: (Drum) Translated from Spanish "Cod Liver Oil With certified color [or "Cod Liver Oil U.S.P."] Each 5 cc contains: Vitamin A 4250 Units and Vitamin D 425 Units * * * Mendez Laboratories of America, Inc., San Juan, Puerto Rico."

RESULTS OF INVESTIGATION: Examination showed that the article in the bulk drums and in the bottles bearing the U.S.P. designation was a golden yellow, non-viscous liquid with the odor of cod liver oil, and that the article in the bottles labeled "with certified color" was a black-colored nonviscous liquid with the odor of cod liver oil, analysis of which showed that it contained External D&C Red No. 14. The article in the bottles was repacked by the dealer and prior to repacking the dealer added color to portions of the article.

LIBELED: 11-29-62, Dist. P.R.

CHARGE: 402(c)—while held for sale, the portion of the repacked article labeled "With certified color" contained External D&C Red No. 14, a color additive, which is unsafe within the meaning of 706(a) since it and its use or intended use were not in conformity with a regulation or exemption in effect; and 403(j)—the repacked article (all bottles) purported to be and was represented as food for special dietary use by reason of its vitamin content and its label failed to bear as required by regulations a statement of the proportion of the minimum daily requirement for vitamins A and D supplied by the article when consumed in a specified quantity during a period of one day.

The article in the drums and in the bottles was alleged also to be misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 7531.

DISPOSITION: 3-12-63. Consent—claimed by Mendez Laboratories of America, Inc., and released under bond for the purpose of destroying the adulterated material and relabeling the material which was not adulterated but was misbranded.

29394. Dietary food wafers. (F.D.C. No. 49587. S. No. 82-114 X.)

QUANTITY: 32 cases, each containing 12 8-oz. boxes, at Nashville, Tenn.

SHIPPED: Between 8-16-63 and 10-22-63, from Evansville, Ind.

LIBELED: 1-7-64, M. Dist. Tenn.

CHARGE: 402(a) (3)—contained insects while held for sale.

DISPOSITION: 3-13-64. Default—destruction.

29395. Vitamin and mineral food supplements. (F.D.C. No. 49418. S. No. 95-373 V.)

QUANTITY: 373 ctns., each containing 728 mineral tablets and 364 vitamin tablets, at Southfield, Mich.

SHIPPED: Between 5-1-62 and 6-30-62, from Beverly Hills, Calif.

RESULTS OF INVESTIGATION: Examination showed that the article contained less than 78 percent of the labeled amount of vitamin B₁₂ and approximately 79 percent of the labeled amount of vitamin A.

LIBELED: 10-17-63, E. Dist. Mich.

CHARGE: 402(b) (1)—while held for sale, valuable constituents of the article, namely, vitamins A and B₁₂ had been in part omitted or abstracted; and 403(a) the label statement "2 Vitamin Tablets and 4 Mineral Tablets Daily